**REMARKS**

Claims 1-17 are pending in the instant application. Claims 6, 10-14 and 16 have been withdrawn from consideration by the Examiner and subsequently canceled without prejudice by Applicants in this response. Claims 1, 8 and 15 have been amended. Claims 9 and 17 have been canceled without prejudice. Support for these amendments is provided in the specification at page 10, line 31 through page 11, line 16; page 13, lines 1-4; page 14, lines 3-10; page 14, line 19 through page 16, line 32; and pages 32-35. No new matter has been added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

**I. Finality of Restriction Requirement**

The Examiner has made final the Restriction Requirement mailed July 27, 2004. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have canceled non-elected claims 6, 10-14 and 16, without prejudice. In light of the finality of this Restriction Requirement, Applicants reserve the right to file a divisional application to the canceled subject matter.

**II. Objection to Specification**

The disclosure has been objected to because it contains embedded hyperlinks and/or other forms of browser executable code. Accordingly, in an earnest effort to advance the prosecution of this case, the specification has been amended to inactivate all embedded hyperlinks by removing "http" and "www" and simply referring to the world wide web. No new matter is added by this amendment and entry is respectfully requested.

Withdrawal of this objection is respectfully requested.

**III. Claim Objections**

Claims 1-5, 7-9, 15 and 17 have been objected to as being drawn to multiple inventions. The Examiner suggests that the claims must be amended to reflect the election. Accordingly, in an earnest effort to advance the prosecution, the claims have been amended to the elected subject matter. No new matter is added by this amendment and entry is respectfully requested.

Withdrawal of this objection is respectfully requested.

**IV. Rejection under 35 U.S.C. 101 and 35 U.S.C. 112, first paragraph**

Claims 1-5, 7-9, 15 and 17 have been rejected under 35 U.S.C. 101 because the Examiner suggests that the claimed invention is not supported by either a substantial utility or a well established utility. These claims have also been rejected under 35 U.S.C. 112, first paragraph. The Examiner suggests that since the claimed invention is not supported by either a substantial asserted utility or a well established utility, one skilled in the art would not know how to use the claimed invention. In particular, the Examiner suggests that there is no teaching whether increased or decreased expression of the nucleic acid sequence is indicative of cancer. The Examiner also suggests that the similarity to Genbank Accession No. AC079988 is indicative of SEQ ID NO;100 being a genomic sequence, not specific for lung but present in every cell in the human body that contains chromosome 2.

Applicants respectfully traverse these rejections.

The instant application claims the benefit of priority from U.S. Provisional Application Serial No. 60/252,500, filed November 21, 2000, the entire contents of which were

incorporated by reference in their entirety into the instant application. See page 1, lines 4-6 of the instant application. In the priority application, SEQ ID NO:61 (corresponding to SEQ ID NO:99 of the instant application) of which SEQ ID NO:100 is the flex sequence (see page 119, lines 19 and 20 of the instant application), was demonstrated by suppression subtractive hybridization of a cDNA library to be a lung cancer specific marker. These experiments described at pages 26 through 28 of the provisional application, which demonstrate utility of the instant claimed invention, have been incorporated into the instant application as Example 1a at page 128. No new matter is added by this amendment.

The case law on utility is quite clear; mere identification of a pharmacological activity of a claimed compound that is relevant to an asserted pharmacological use provides an immediate benefit to the public and thus satisfies the utility requirement. Nelson v. Bowler, 626 F.2d 853, 206 USPQ 881, 883 (CCPA 1980). Clearly identification of SEQ ID NO:61 corresponding to SEQ ID NO:99 of the instant application and which SEQ ID NO:100 is the flex sequence of, as being a lung cancer specific

marker constitutes a pharmacological activity relevant to the asserted use of SEQ ID NO:100 as a diagnostic for lung cancer, thus satisfying the utility requirement.

Withdrawal of these rejections under 35 U.S.C. § 101 and 112, first paragraph is therefore respectfully requested.

**V. Rejection of Claims 1-5, 7-9, 15 and 17 under 35 U.S.C. 112, first paragraph - written description**

Claims 1-5, 7-9, 15 and 17 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner suggests that the claims are drawn to a genus of nucleic acid molecules with various degrees of variations from SEQ ID NO:100, a genus of vectors containing said nucleic acid molecules, a genus of host cells containing said vectors, and a method for producing a genus of polypeptides using the host cells. The Examiner suggests that only the isolated nucleic acid comprising SEQ ID NO:100, but not the full breadth of the claim meets the written description requirement.

Applicants respectfully traverse this rejection.

At the outset, it is respectfully pointed out that claim 1 has been amended and is now drawn to an isolated nucleic acid molecule comprising a nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 100 or part thereof, a nucleic acid molecule that selectively hybridizes under stringent hybridization conditions of 50% formamide/6X SSC at 42°C for at least 10 hours or 6X SSC at 68°C without formamide for at least 10 hours to the nucleic acid molecule of SEQ ID NO:100; a nucleic acid molecule having at least 95% sequence identity to the nucleic acid molecule of (a), or a naturally occurring allelic variant of the nucleic acid molecule of (a). Applicants respectfully disagree with the characterization of this claim, limited to a specific nucleic acid sequence or part thereof and sequences with shared identity thereto, which hybridize under stringent conditions thereto or which are naturally occurring allelic variants thereof, as being drawn to a genus of nucleic acid molecules. In accordance with MPEP § 806.04(e) a genus is inclusive of two or more species, which are usually "unrelated" and/or "independent". Nucleic acid molecules with a defined shared identity to SEQ ID NO:1, which hybridize under defined stringent

conditions to SEQ ID NO:100 or which are naturally occurring allelic variants of SEQ ID NO:1 can hardly be considered unrelated.

Further, the written description requirement of 35 U.S.C. § 112, first paragraph, as set forth in MPEP § 2163.02 requires that the specification set forth definitive structural features of the claimed polynucleotides so that one of skill in the art can predictably identify the encompassed molecules as being identical to those now claimed. MPEP 2163.02 also requires that the specification show that applicant was in possession of the claimed invention. Part (b) of claim 1 has been amended and is now drawn to a nucleic acid molecule that selectively hybridizes to the nucleic acid molecule of SEQ ID NO:100 of under stringent hybridization conditions. The stringent conditions are specifically defined in the claim so that one of skill in the art can predictably identify molecules identical to part (b) of this claim. Further, Applicants' possession of stringently hybridizing sequences is clearly evidenced in the specification at pages 14-16 wherein detailed teachings regarding determining nucleic acid molecules which

hybridize under stringent conditions are set forth. Part (c) of claim 1 has also been amended to be drawn to a nucleic acid molecule that has at least 95% sequence identity to the nucleic acid molecule of SEQ ID NO:1. This claim as amended clearly defines a definitive structural feature so that one of skill can predictably identify a molecule as falling within the scope of part (c). Further, methods for determining nucleic acid molecules with at least 95% sequence identity are set forth in detail at pages 14 thus evidencing Applicants' possession of this invention. In addition, naturally occurring allelic variants of SEQ ID NO:100 are described at page 34 of the instant specification, thus evidencing possession of this aspect of the present invention as well.

Accordingly, claim 1 as amended and claims dependent therefrom meet the written description requirements of 35 U.S.C. 112, first paragraph as set forth in MPEP 2163.02.

The Examiner also suggests that there is inadequate written description with respect to claim 9 drawn to a method of producing a polypeptide using the claimed nucleic acid because the specification does not teach the structure of the polypeptide that SEQ ID NO:100 encodes. While

Applicants do not agree with the Examiner, in an earnest effort to advance the prosecution, claim 9 has been canceled without prejudice.

Withdrawal of this rejection is respectfully requested in light of the amendments to the claims and the above remarks.

**VI. Rejection of Claims 1-5, 7-9, 15 and 17 under 35 U.S.C. 112, first paragraph - lack of enablement**

Claims 1-5, 7-9, 15 and 17 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The Examiner suggests that the specification does not teach whether SEQ ID NO:100 is over-expressed or under-expressed in lung cancer or any other lung disease nor does it teach nucleic acids that selectively hybridize or have 60% identity to SEQ ID NO:100.

Applicants respectfully traverse this rejection.

As discussed in Section IV, supra, the specification has been amended to include Example 1 from U.S. Provisional Application Serial NO. 60/252,500, from which the instant case claims priority. This example establishes SEQ ID NO:100 as lung cancer specific thus mooting the Examiner's concerns that the specification does not teach whether SEQ

ID NO:100 is over-expressed or under-expressed in lung cancer.

Further, Applicants have amended part (b) and (c) of claim 1 to be drawn to a nucleic acid molecule that selectively hybridizes under stringent hybridization conditions of 50% formamide/6X SSC at 42° C for at least 10 hours or 6X SSC at 68° C without formamide for at least 10 hours to the nucleic acid molecule of SEQ ID NO:100 or a nucleic acid molecule having at least 95% sequence identity to the nucleic acid molecule of SEQ ID NO:100. Methodologies for identifying such sequences are expressly taught in the specification at pages 14-16. Further, detailed methodologies for use of such sequences are taught throughout the specification. Thus, the instant specification clearly teaches one of skill in the art how to make and use the claimed sequences, thus meeting the enablement requirements of 35 U.S.C. 112, first paragraph.

The Examiner also suggests with respect to claim 17 that undue experimentation would be required since no protein encoded by SEQ ID NO:100 is taught. While Applicants respectfully disagree with the Examiner, in an

earnest effort to advance the prosecution of this case, claim 17 has been canceled without prejudice.

Further, with respect to claim 8, Applicants have amended this claim in accordance with the Examiner's suggestion to be drawn to an isolated host cell.

Withdrawal of these rejections is therefore respectfully requested in light of the amendments to the claims and the above remarks.

**VII. Rejection of Claims 1-5, 7, 8, 15 and 17 under 35 U.S.C. 102**

Claims 1-5, 7, 8, 15 and 17 have been rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,368,794. The Examiner suggests that SEQ ID NO:3 of the '793 patent has 63.5% sequence identity to SEQ ID NO:100.

Claims 1, 3-5, 7, 8, 15 and 17 have also been rejected under 35 U.S.C. 102(a) as being anticipated by Genbank Accession No. AC079988. The Examiner suggests that Genbank Accession No. AC079988 contains an insert having 94.6% sequence identity to SEQ ID NO:100.

It is respectfully pointed out, however, that part (c) of claim 1 has been amended in accordance with teachings at page 14 to be drawn to a nucleic acid molecule with at

least 95% sequence identity to SEQ ID NO:100. Since neither of the cited references teaches a sequence with this identity to SEQ ID NO:100, these references cannot anticipate the claim as amended.

Withdrawal of these rejections is therefore respectfully requested.

**VIII. Conclusion**

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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Date: **March 9, 2005**

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